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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,395	02/08/2002	Michael L. Bell	2030-045	9989

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PATENT LEGAL DEPARTMENT/A-42-C
BECKMAN COULTER, INC.
4300 N. HARBOR BOULEVARD
BOX 3100
FULLERTON, CA 92834-3100

EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,395	BELL, MICHAEL L.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *5-11 and 15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-4 and 12-14, in the reply filed on 19 September 2006 is acknowledged. The traversal is on the ground(s) that the methods of groups I-III all relate to a unifying inventive concept and should therefore be examined together. This is not found persuasive because a unifying inventive concept between methods does not provide a basis for restriction and is therefore an invalid reason for grouping claims together. The methods of each of groups I-III require elements that are not required of the other groups. A chemical interference and steric interference are distinct because they provide interference that is chemical and physical, respectively, and require different elements to provide for chemical or steric interference. Therefore chemical and steric interference require different elements and are not related as genus and species. Furthermore, claims 1 and 12 link claims 3 and 5, and are included in both groups I and II. The linked claims 3 and 5 are restricted from each other because claims 3 and 5 each require elements that are not required of the other claim (a porous structure and a molecule bound to the structure) and the search for claim 3 would not encompass a search for claim 5 and a search for claim 5 would not encompass a search for claim 3. Therefore these inventions are independent and distinct. Furthermore, since the methods are independent and distinct, the product of group IV can be used in any of the materially different processes and is therefore not included in the methods of groups I-III.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3 are unclear because the claim recites "steric interference" that hinders the ability of the binding ligand to bind to the target analyte and also recites "determining the concentration of the target analyte". Steric interference is defined as decreasing the rate or extent of binding, but not eliminating binding. It is unclear how the concentration of target analyte of the extent of binding is decreased by steric interference. It is vague as to whether an accurate concentration of analyte can be determined if the extent of binding is reduced.

Claims 1 and 3 are further vague because it is unclear what the recited "other target analyte(s)" and "all other binding ligand(s)" are. It is unclear whether additional binding ligands are immobilized to the support or additional binding ligands are present on the support or whether a plurality of the same binding ligands are immobilized on the porous support. It is confusing as to whether the hindered binding is merely hindering binding of the analyte to a single binding ligand or whether binding with all binding ligands of the same type are hindered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al. (US 4,912,032).

Hoffman et al. teach a method comprising: providing for at least one target analyte to be analyzed a binding ligand of the target analyte that is bound to a solid support (polymer gel includes a first component of the binding pair, col. 4, lines 57-60; col. 10, lines 23-51); wherein the ability of the binding ligand to bind to the target analyte is hindered by a steric interference (pore sizes are increased and decreased to increase and decrease diffusion into the gel, therefore when the pore sizes are decreased the rate of binding is decreased and the binding is therefore hindered by steric interference, col. 8, lines 60-65; diffusion rate is slowed which slows the rate of binding of any immobilized ligands, and therefore steric hindrance is present, col. 14, lines 10-20); and determining the presence of the target analyte by determining the extent of binding between the target analyte and the solid-support binding ligand for the target analyte (assaying antigen binding to the first binding partner immobilized within the gel, col. 15, line 62-col. 16, line 4; pores are made smaller to slow diffusion of reactants which include ligands, col. 18, lines 23-27). Although Hoffman et al. do not specifically recite that the extent of binding is determined, when an immunoassay is performed between an antigen and immobilized antibody, the extent of binding is determined to determine the presence of target analyte (the antigen). Furthermore, although Hoffman et al. do not specifically teach that the steric interference does not hinder the binding of all other target analyte to all other binding ligands, because the steric hindrance is provided by a porous solid support, and the support has the same features as those required by the instant claim, the steric interferences taught by Hoffman et al. would be capable of not hindering binding of other target analyte to other binding ligands. Since it is unclear whether the claim actually requires additional binding ligands or target analyte, these elements are not required for the method of the instant claims.

With respect to claims 2 and 3, Hoffman et al. teach a porous solid support providing steric interference, wherein the binding ligand is bound within the pores of the support

(polymer gel is porous, pores provide steric interference, ligands are immobilized within the gel pores, col. 9, lines 47-57).

Regarding claim 4, Hoffman et al. teach the support being a porous polymeric material (polymer gel, col. 3, lines 37-39).

4. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Sato et al. (Note: Effect of pore size of porous bead carriers immobilizing antibody on IgE adsorption, 1986, Journal of Biomedical Materials Research, Vol. 20, pages 853-858).

Sato et al. teach a method comprising: providing a binding ligand bound to a solid support (IgG antibodies are immobilized on porous glass beads, pg. 853, last sentence), wherein the ability of the binding ligand to bind to the target analyte is hindered by steric interference (pore size hindered extent of binding, which means that steric interference prevented binding, pg. 856, second paragraph); and determining the extent of binding between the target analyte and the solid support bound binding ligand of the target analyte (efficiency of binding between the immobilized ligand and the IgE antibody in the sample was analyzed, therefore the extent of binding was determined, pg. 856, second paragraph-pg. 857). Although Sato et al. do not specifically teach the steric interference not hindering the binding of other target analytes to all other binding ligands, the claim does not specifically require other target analyte or other binding ligands. Furthermore, because the steric interference is provided by the solid support as recited in the instant claims, the steric interference is capable of not hindering binding of other target analyte to other target ligands.

With respect to claims 2-4, Sato et al. teach the steric interference provided by the solid support (small pore size decreases diffusion and therefore creates steric interference, pg. 856, second paragraph), and the solid support being porous glass beads (pg. 853, last

sentence) that has controlled pore size (pg. 856, second paragraph), wherein the ligands are bound within the pores of the porous material (pg. 853, last sentence).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al. (Note: Effect of pore size of porous bead carriers immobilizing antibody on IgE adsorption, 1986, Journal of Biomedical Materials Research, Vol. 20, pages 853-858) in view of McHugh (Flow Microsphere Immunoassay for the Quantitative and Simultaneous Detection of Multiple soluble analytes, Methods in Cell Biology, pgs. 575-595).

Sato et al. teach a method for assaying target analyte by determining binding between the target analyte and the ligand for the target analyte, but fail to teach incubating the support with a detectably labeled binding ligand-binding molecule and determining the presence of the detectable label.

McHugh teaches a flow cytometry assay (587, Heterogeneous Noncompetitive FMIA for the detection of antibody to antigen X, step 7) wherein the extent of binding between a

target analyte and a binding ligand bound to a solid support comprises: binding a ligand bound to the solid support to a target analyte (pg. 576, first paragraph; pg. 581, passive (noncovalent) coating and passive coating; pg. 587, heterogeneous noncompetitive FMIA for the detection of antibody to antigen X, step 1); incubating the solid support in the presence of a detectably labeled binding ligand-binding molecule (pg. 576, last sentence-pg. 577, first sentence; pg. 587, Heterogeneous Noncompetitive FMIA for the detection of antibody to antigen X, steps 5-6); and determining the presence of the detectable labeled binding ligand binding bound to the solid support ligand of the target analyte (587, Heterogeneous Noncompetitive FMIA for the detection of antibody to antigen X, step 7-8), in order to detect multiple analytes in a single sample.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Hoffman et al., incubation the analyte and binding ligand with a detectable labeled binding ligand-binding molecule and determining the presence of the detectable label as taught by Sato et al., in order to provide a more sensitive detection of the target analyte.

6. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al. (US 4,912,032) in view of McHugh (Flow Microsphere Immunoassay for the Quantitative and Simultaneous Detection of Multiple soluble analytes, Methods in Cell Biology, pgs. 575-595).

Hoffman et al. teach a method for assaying target analyte by determining binding between the target analyte and the ligand for the target analyte, but fail to teach incubating the support with a detectably labeled binding ligand-binding molecule and determining the presence of the detectable label.

McHugh teaches a flow cytometry assay (587, Heterogeneous Noncompetitive FMIA for the detection of antibody to antigen X, step 7) wherein the extent of binding between a

target analyte and a binding ligand bound to a solid support comprises: binding a ligand bound to the solid support to a target analyte (pg. 576, first paragraph; pg. 581, passive (noncovalent) coating and passive coating; pg. 587, heterogeneous noncompetitive FMIA for the detection of antibody to antigen X, step 1); incubating the solid support in the presence of a detectably labeled binding ligand-binding molecule (pg. 576, last sentence-pg. 577, first sentence; pg. 587, Heterogeneous Noncompetitive FMIA for the detection of antibody to antigen X, steps 5-6); and determining the presence of the detectable labeled binding ligand binding bound to the solid support ligand of the target analyte (587, Heterogeneous Noncompetitive FMIA for the detection of antibody to antigen X, step 7-8), in order to detect multiple analytes in a single sample.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Hoffman et al., incubation the analyte and binding ligand with a detectable labeled binding ligand-binding molecule and determining the presence of the detectable label as taught by McHugh, in order to provide a more sensitive detection of the target analyte.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Yu
Patent Examiner
Art Unit 1641

LONG V. LE 12/07/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600